



UNITED STATES DEPARTMENT OF COMMERCE
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08/321,571

SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/321,571 10/10/94 ERSEK

R	010521.CGO
EXAMINER	

BRITTINGHAM, D

ART UNIT	PAPER NUMBER
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20

33M1/1031

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3308
DATE MAILED:

10/31/95

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 7-28-95 ☒ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), — days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice of Draftsman's Patent Drawing Review, PTO-848. |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____ |

Part II SUMMARY OF ACTION

1. ☒ Claims 80-97 and 99-100 are pending in the application.
Of the above, claims _____ are withdrawn from consideration.
2. ☒ Claims 1-79, 98 and 102-120 have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 80-97 and 99-100 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-848).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

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Part III DETAILED ACTION

Claim Rejections - 35 USC §102/§ 103

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

2. The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

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3. Claims 80 and 93 are rejected under 35 U.S.C. § 102(E) as anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over Berg et al.

Berg et al. disclose an injectable particulate implantation system comprising generally soft elastic particles dispersed in non-retentive physiological medium. The particles have rough surface texture forming surface irregularities. While Berg et al. does not specifically state that the microporous collagen beads are elastic or soft, it is well established in the art that collagen is generally malleable and somewhat resilient especially when compared to metallic or ceramic particles. Examiner contends that the inherent properties of collagen fall within the range of "generally soft, malleable and elastic" as broadly claimed.

4. Claim 99 is rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over Miyata et al.

Miyata et al. disclose an injectable particulate implantation system comprising generally soft elastic particles dispersed in non-retentive physiological medium. The particles have rough surface texture forming surface irregularities. While Miyata et al. does not specifically state that the microporous collagen beads are elastic or soft, it is well established in the art that collagen is generally malleable and somewhat resilient

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especially when compared to metallic or ceramic particles. Examiner contends that the inherent properties of collagen fall within the range of "generally soft, malleable and elastic" as broadly claimed.

Claim Rejections - 35 USC § 101

5. Claims 81-92, 94-97 and 100 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 5,258,028. Although the conflicting claims are not identical, they are not patentably distinct from each other because these claims are obvious variants of the earlier patented claims.

Response to Amendment

6. Applicant's arguments filed 28 June 1995 have been fully considered but they are not deemed to be persuasive.

With respect to Applicant's arguments regarding claims 80 and 93, Examiner disagrees. Claim 80, at line 4, does NOT contain the limitation "non-resorbing." Therefore, Applicant's arguments are moot.

With respect to Applicant's arguments regarding claim 99, Examiner disagrees. Collagen fibrils are not necessarily

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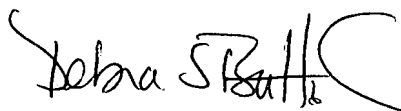
resorbable as proved by the used of collagen fibrils in intraocular implants. Therefore, this argument is moot.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication should be directed to Debra S. Brittingham at telephone number (703) 308-3401.



**DEBRA S. BRITTINGHAM
PATENT EXAMINER
GROUP 3300**